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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,844	06/23/2003	Manne Satyanarayana Reddy	BULK 3.0-018	9550

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EXAMINER	
WARD, PAUL V	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Advisory Action After the Filing of an Appeal Brief	Application No. 10/601,844	Applicant(s) REDDY ET AL.	
	Examiner PAUL V. WARD	Art Unit 1624	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The reply filed 20 March 2008 is acknowledged.

1. ☐ The reply filed on or after the date of filing of an appeal brief, but prior to a final decision by the Board of Patent Appeals and Interferences, will not be entered because:

   a. ☐ The amendment is not limited to canceling claims (where the cancellation does not affect the scope of any other pending claims) or rewriting dependent claims into independent form (no limitation of a dependent claim can be excluded in rewriting that claim). See 37 CFR 41.33(b) and (c).

   b. ☐ The affidavit or other evidence is not timely filed before the filing of an appeal brief. See 37 CFR 41.33(d)(2).

2. ☐ The reply is not entered because it was not filed within the two month time period set forth in 37 CFR 41.39(b), 41.50(a)(2), or 41.50(b) (whichever is appropriate). Extensions of time under 37 CFR 1.136(a) are not available.

   Note: This paragraph is for a reply filed in response to one of the following: (a) an examiner's answer that includes a new ground of rejection (37 CFR 41.39(a)(2)); (b) a supplemental examiner's answer written in response to a remand by the Board of Patent Appeals and Interferences for further consideration of rejection (37 CFR 41.50(a)(2)); or (c) a Board of Patent Appeals and Interferences decision that includes a new ground of rejection (37 CFR 41.50(b)).

3. ☒ The reply is entered. An explanation of the status of the claims after entry is below or attached.

4. ☐ Other: _____

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624

/PAUL V WARD/
Examiner, Art Unit 1624

STATUS OF THE CLAIMS: The rejection of claims 1-18 under 35 U.S.C. 102, 103 and 112, set forth in the Office action dated November 17, 2006 has been maintained for the reasons of record for the reasons set forth herein.

102(b): Applicant claims amorphous levocetirizine dihydrochloride, amorphous levocetirizine dihydrochloride free of crystalline forms of cetirizine dihydrochloride, and compositions comprising the levocetirizne dihydrochloride. Additionally, Applicant claims compositions of levocetirizine dihydrochloride containing a moisture content ranging from about 0.3 % to 12% using the KF method.
Tang teaches the exact amorphous levocetirizine dihydrochloride and falls within the range of Applicant's compounds. (See Abstract, pg. 311, Fig. 1 pg. 311, and Figures 2-3 on pg. 312). Since Tang teaches the exact compounds, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).
Pflum teaches the exact amorphous levocetirizine dihydrochloride and falls within the range of Applicant's compounds. (See Abstract, pg. 110, Fig. 1 pg. 110, and Tables 2-3 on pg. 111 and left col.). Additionally, on page 111, left hand column, and on page 112, right hand column (last paragraph), Pflum teaches that the levocetirizine contain yields of 79% and 99%. Since Pflum teaches the exact compounds, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).
Van de Venne teaches compositions comprising levocetirizine dihydrochloride with one or more pharmaceutically acceptable excipients, and falls within the range of Applicant's compounds. (See Abstract, col. 3 lines 45-60, col. 5, lines 10-55, and Table in col. 6). Since Van de Venne teaches the exact compositions, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

103: Van de Venne teaches compositions comprising levocetirizine dihydrochloride (See Abstract and columns 3-6). The claims differ from the reference by reciting the composition containing a moisture content.
Thus, Van de Venne does not teach Applicant claims in the same format as claimed by applicant, however, one skilled in the art would find the differences in the teaching to be negligible. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Van de Venne to obtain the compositions as claimed in the instant application. Obviousness based on similarity of structure and functions entails motivation to make the clamed compound in expectation that compounds similar in structure will have similar properties. Therefore, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for levocetirizine compositions. See In re Payne, 203 USPQ 245 (CCPA 1979). Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.
Applicant argues that the prior art does not disclose "amorphous" levocetrizine dihydrochlorides.
The amorphous form is an obvious variation, which one is motivated to obtain because of the expected solubility advantage. Note this from the conclusion of Hancock, Pharm. Res. 17(4) 397 (2000): "Amorphous pharmaceuticals are markedly more soluble than their crystalline counterparts…Based on a comparison with polymorphic crystal forms of drug compounds the clinical relevance of solubility increases for amorphous drug forms is likely to be significant, even in systems which are only partially amorphous.
Thus, Applicant arguments are not persuasive. Therefore, the rejection of claims 1-18 under 35 U.S.C. 102, 103 and 112, set forth in the Office action dated November 17, 2006 has been maintained for the reasons of record for the reasons set forth herein.